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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 575,377	05.22.2000	James J. Hickman	HICHMAN-100	2330

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PATENT ADMINISTRATOR
KATTEN MUCHIN ZAVIS ROSENMAN
525 WEST MONROE STREET
SUITE 1600
CHICAGO, IL 60661-3693

[REDACTED] EXAMINER

ALLEN, MARIANNE P

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1631

DATE MAILED: 06/11/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/575,377	HICKMAN, JAMES J.
	Examiner Marianne Allen	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 March 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 28-49 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-27 is/are rejected.
- 7) Claim(s) _____ is/are objected to
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The original oath lists the wrong provisional application number and filing date for the provisional application. See listing of 60/132,275 with filing date 1/6/99 instead of 60/135,275 with filing date 5/21/99.

Information Disclosure Statement

Applicant is encouraged to file an information disclosure statement.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-27, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that there is no burden of search. This is not found persuasive because burden of search has been previously established.

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Claim Rejections - 35 USC § 112

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “accompanying software.” It appears this is intended to mean a computer readable medium containing particular executable instructions, but this is not clear.

Claim 4 lacks antecedent basis in claim 1 for “processing instructions.” See also claim 14. The claim also uses improper Markush language. The claim should recite “the group consisting of calcium channels, **and** combinations thereof.” See also claim 7.

Claim 11 is unclear as to when the stem cell is exposed to a differentiating factor.

Claim 13 is confusing in reciting “similar molecules.” It cannot be determined how similar the molecule must be to meet the limitation of the claims.

Claim 15 is confusing in reciting “cadherins” twice.

Claim 21 is confusing in reciting “and the like.” It cannot be determined which other polymers meet the limitation of the claims.

Claim 22 is confusing in reciting “can be characterized.” It cannot be determined what the criteria are to distinguish one from the other. It is unclear what must be attracted or repelled.

Claim 23 is confusing in requiring a detector circuit. It is unclear if this forms part of the device or accompanying software.

Claim 24, line 4, contains a typographical error, “ore.”

Claim 27 is confusing in reciting “deconvolution leads to information on pathways or functional categories affected in the cell.” It is not clear what the metes and bounds of functional category are nor what deconvolution analysis provides the recited information.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Applicant is being given benefit to the instant filing date of 5/22/00 and denied benefit to the priority date of 5/21/99 for provisional application 60/135,275. It is noted that the provisional application appears to be a compilation of two grant proposal documents and does not disclose or contemplate the generic invention as presently recited in the claims.

Claims 1-8, 12-14, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Jung et al. (*Journal of Vacuum Science & Technology*, 16(3):1182-1188, 1998).

Jung et al. discloses a biosensor system comprising a solid state electrode array where the microelectrodes are electroplated with platinum black and a silane SAM was formed on the array. The gold electrodes have an insulating silicon nitride top layer. The arrays were used to detect extracellular potentials and variations from cell cultures of beating rat myocytes and rat spinal cord cells. See in particular abstract and methods. The system includes recording devices that include software which analyzes wave forms. See for example Figures 6 and 7. Such software routinely contains functionalities to compare and contrast waveforms from different experiments.

With respect to claim 4, it would have been well known that the cell cultures used by Jung et al. possessed sodium, potassium and calcium channels.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 18-19, and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkholder et al. (U.S. Patent No. 6,377,057) in view of Jung et al.

Applicant is being given benefit to the instant filing date of 5/22/00 and denied benefit to the priority date of 5/21/99 for provisional application 60/135,275. It is noted that the provisional application appears to be a compilation of two grant proposal documents and does not disclose or contemplate the generic invention as presently recited in the claims.

Borkholder et al. discloses a biosensor for use in evaluating the effect of test compounds on ion channels in excitable cells. Borkholder et al. contemplates using cells which are genetically altered by exogenous and endogenous gene manipulation as well as stem cells that are able to differentiate into excitable cells. Computer software and systems for action potential analysis are disclosed. (See abstract; claims; figures; column 7, line 45, through column 8, line 13; column 11, line 5, through column 12, line 40; column 14, lines 14-35.) Although hippocampal cells (see claim 8) are not specifically mentioned at column 11, lines 5-25, these neuronal cells would have been routinely used by those in the art at the time of the invention for

electrophysiological recording. (See for example, page 2, lines 17-19, and page 5, lines 26-28, of the specification in support of this assertion.) Borkholder et al. doesn't clearly disclose a microelectrode as set forth in the claims; however, Borkholder et al. makes clear that any other suitable biosensor could be used in the disclosed system and method.

Jung et al. is applied as above and does teach a microelectrode as set forth in the claims.

It would have been obvious to use the microelectrode of Jung et al. in the system and method of Borkholder et al. One would have been motivated to do so as a matter of substituting another suitable and known biosensor.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kovacs et al. (U.S. Patent No. 5,981,268) discloses hybrid biosensors evaluating biological characteristics of excitable cells, including stem cells that can be differentiated, and evaluating adhesion promoting agents such as SAMs.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Art Unit: 1631

Marianne P. Allen

Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa

June 10, 2002